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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,782	08/13/2001	Robert O. Ralston	154.206	1144

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EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/929,782

Applicant(s)

RALSTON ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20- 23, and 56- 79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20- 23, and 56- 79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 20- 23 and 56- 79 are under consideration in this action.

#### ***Rejections Withdrawn***

##### ***Claim Rejections - 35 USC § 102/ 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Houghton (EP 318 216).

Houghton discloses an isolated antibody that is reactive with asialoglycoproteins of HCV E1 and/or E2 (at least at page 56, lines 33- 44).

Applicant's argument is persuasive as to the binding of the cited antibodies and the rejection is withdrawn.

#### ***Rejections Maintained***

##### ***Claim Rejections - 35 USC § 112***

Claims 20- 23 and 56- 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Applicant has amended the "directed against" to be "binds to" and added the further limitation that the antibody does not bind to other HCV proteins.

Applicant argues that "binds to" is sufficiently definite and that the antibody binds to a particular protein.

Applicant's argument has been fully considered and not found persuasive.

The metes and bounds of "binds to", used to describe the antibody is not clear and is not defined in the specification in such a way to know what specificity is envisioned. It is not clear that the antibody is directed against the asialoglyco part, the amino acid residues or conformation of native protein. It is not clear how this antibody differs from one that binds to sialated glycoprotein. Thus, not knowing the basis of specificity, the claims are not clear.

The rejection is maintained.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigen production, does not reasonably provide enablement for specific antibodies and were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for concept of using an antigen to make an antibody, does not reasonably provide enablement for making an antibody for the stated antigen.

Applicant argues the claims have been amended to recite "binds to" and this overcomes the basis of the rejection.

Applicant's argument has been fully considered and not found persuasive.

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As discussed above in the 112 second rejection, it is not clear what specificity is required of the antibody and how this is different from other antibodies. Without knowing this, it is not possible to know when the antibody of the invention is made.

The rejection is maintained.

Claims 20- 23, and 56- 79 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues the specification meets the specification conveys with reasonable clarity that applicant was in possession of what is claimed, that applicant does not have to supply information that is well known in the art, that PTO Example 16 describes the claimed antibodies.

Applicant's argument has been fully considered and not found persuasive.

The specification does not contemplate all the antibodies recited in the claims as they now stand. The Disclosure of the Invention (pages 3 and 4) does not mention antibodies. The level of skill in the art of antibodies was high at the time of filing; however, the specification contains no reference to physical properties or structure of the antibody nor does it teach antibodies binding to E1 or E2. As Applicant states, they **contemplated** antibodies (emphasis added). Applicant cites from *Vas-Cath Inc. v. Mahurkar* ((CAFC, 1991) 19 USPQ2d 1111), which states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or

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she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Applicant may have contemplated the antibodies but did not convey in the specification that they were in fact in possession of the claimed antibodies.

As discussed above the 112, second paragraph, rejection, it is not clear what the antibody binds to.

The level of skill in the art of making and screening antibodies is high as indicated in the previous action. Without knowing what the antibodies bind to, it is not possible to screen for them.

Applicant cites PTO Example 16 relating to antibodies as directly relevant to the instant claims. The facts of the example does not follow that instant claims. The instant antibody binds to an asialoglycoprotein E1 and/or E2 but not other HVC proteins. The antibody of the present claims binds to an asialoglycoprotein E1 and/or E2 but not other HVC proteins. This requires that the antibody not bind to any asialoglycoproteins or bind to E1/E2 that is not asialoglycosylated. The instant "antigen" is more complex than the example because it is glycosylated and the recited antibody is different because it also has to not bind to other HCV proteins. While the analysis of the example provided by the Office may be correct for one fact situation, each application is handled on a case by case basis depending on the facts of each situation. The scope of the example and the instant claims are not the same.

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The rejection of record is maintained.

### ***New Rejections***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20- 23, and 56- 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a new matter rejection.

The limitation "does not bind to other HCV proteins" was added to claims 20 and 56.

Applicant is requested to point out support for the added limitation because it is not obvious to the Examiner.

### ***Conclusion***

All claims remain rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Myron G. Hill  
Patent Examiner  
April 5, 2004



MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800

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